

### **REMARKS**

Applicants thank the Examiner for the thorough examination given the present application.

#### **Status of the Claims**

Claims 5, 7, and 13-14 are pending in the above-identified application. In view of the following remarks, Applicants respectfully request that the Examiner withdraw all rejections and allow the currently pending claims.

#### **Issues under 35 U.S.C. § 103(a)**

Claims 5, 7, and 13-14 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Ueda et al. '103 (US 6,831,103) in view of Hamilton (J. Neurol. Neurosurg Psychiat, 1960, 23, 56). Applicants respectfully traverse. Reconsideration and withdrawal of this rejection are respectfully requested based on the following considerations.

#### **Legal Standard for Determining Prima Facie Obviousness**

MPEP 2141 sets forth the guidelines in determining obviousness. First, the Examiner has to take into account the factual inquiries set forth in *Graham v. John Deere*, 383 U.S. 1, 17, 148 USPQ 459, 467 (1966), which has provided the controlling framework for an obviousness analysis. The four *Graham* factors are:

- (a) determining the scope and content of the prior art;
- (b) ascertaining the differences between the prior art and the claims in issue;
- (c) resolving the level of ordinary skill in the pertinent art; and
- (d) evaluating any evidence of secondary considerations.

*Graham v. John Deere*, 383 U.S. 1, 17, 148 USPQ 459, 467 (1966).

Second, the Examiner has to provide some rationale for determining obviousness. MPEP 2143 sets forth some rationales that were established in the recent decision of *KSR International Co. v Teleflex Inc.*, 82 USPQ2d 1385 (U.S. 2007).

As the MPEP directs, all claim limitations must be considered in view of the cited prior art in order to establish a *prima facie* case of obviousness. See MPEP 2143.03.

*The Present Invention*

Independent claim 5 recites:

A method for treating an individual having at least symptoms of feelings of guilt, suicide, and retardation: psychomotor, associated with a mood disorder, each symptom being assessed according to the assessment method by the Hamilton scale, comprising

administering an effective amount of a composition comprising theanine to the individual in need of treatment, sufficient to reduce a score of the Hamilton scale,

wherein said mood disorder is distinct from mood disorders associated with menstruation; and

wherein said individual is a normofolatemc patient.

*Distinctions over the Cited References*

As shown above, the present invention recites that at least three symptoms of feelings of guilt, suicide, and retardation: psychomotor are treated by theanine. This feature is not disclosed by Ueda et al. '103. Also, in the assessment for depression regarding 21 items (symptoms) with the Hamilton scale, a statistically significant effect was shown at Day 7 for only five symptoms, including the claimed three symptoms, among the 21 symptoms (see Table 1 of the present specification; *reproduced below from the printed publication of the present specification for the Examiner's convenience*). The cited references fail to disclose that at least the three symptoms among the 21 symptoms can be treated while showing effectiveness with statistical significance. When theanine is administered in Ueda et al. '103, one of ordinary skill in the art would not expect that only specific symptoms are improved when improvement in many symptoms of depression are not shown by the Hamilton scale.

TABLE 1

Items	Group Administered with Theanine-Formulated Tablet			
	Before Intake	Day 7	Day 14	Day 21
1. Depressed Mood	2.833 ± 0.322	2.000 ± 0.389**	1.083 ± 0.336**	0.583 ± 0.288**
2. Feelings of Guilt	2.667 ± 0.333	2.000 ± 0.369*	1.250 ± 0.351**	0.833 ± 0.322**
3. Suicide	2.750 ± 0.372	2.000 ± 0.369*	1.167 ± 0.322**	0.667 ± 0.333**
4. Insomnia Early	0.333 ± 0.142	0.583 ± 0.149	0.583 ± 0.163	0.583 ± 0.193
5. Insomnia Middle	0.250 ± 0.131	0.333 ± 0.142	0.500 ± 0.195	0.583 ± 0.193
6. Insomnia Late	0.250 ± 0.131	0.250 ± 0.131	0.667 ± 0.188	0.583 ± 0.149*
7. Work and Activities	0.917 ± 0.260	1.167 ± 0.241	0.917 ± 0.229	1.000 ± 0.213
8. Retardation: Psychomotor	2.833 ± 0.207	1.917 ± 0.288**	1.250 ± 0.351**	0.833 ± 0.345**
9. Agitation	0.917 ± 0.193	1.000 ± 0.174	1.000 ± 0.174	0.917 ± 0.149
10. Anxiety(Psychological)	0.833 ± 0.241	0.833 ± 0.207	1.000 ± 0.213	1.000 ± 0.213
11. Anxiety Somatic	0.833 ± 0.297	0.750 ± 0.279	0.833 ± 0.271	0.750 ± 0.218
12. Somatic Symptoms (Gastrointestinal)	0.417 ± 0.193	0.500 ± 0.195	0.500 ± 0.151	0.667 ± 0.142
13. Somatic Symptoms General	0.917 ± 0.260	0.833 ± 0.241	0.583 ± 0.193	0.583 ± 0.193
14. Genital Symptoms	0.417 ± 0.229	0.500 ± 0.230	0.417 ± 0.229	0.500 ± 0.230
15. Hypochondriasis	1.333 ± 0.256	1.250 ± 0.279	1.250 ± 0.279	1.167 ± 0.241
16. Diminished Insight	1.667 ± 0.188	1.083 ± 0.260*	0.417 ± 0.229**	0.333 ± 0.225**
17. Loss of Weight	1.083 ± 0.193	1.000 ± 0.246	1.000 ± 0.213	0.917 ± 0.193
18. Diurnal Variation - Morning or Evening	0.500 ± 0.195	0.583 ± 0.193	0.417 ± 0.149	0.500 ± 0.151
19. Depersonalization and Derealization	0.833 ± 0.207	0.750 ± 0.218	0.750 ± 0.218	0.750 ± 0.218
20. Paranoid Symptoms	1.083 ± 0.260	1.083 ± 0.229	0.833 ± 0.241	0.750 ± 0.218
21. Obsessional and Compulsive Symptoms	0.500 ± 0.195	0.583 ± 0.193	0.583 ± 0.193	0.583 ± 0.149

Items	Group Administered with Control Tablet			
	Before Intake	Day 7	Day 14	Day 21
1. Depressed Mood	2.833 ± 0.241	2.333 ± 0.188	2.000 ± 0.302	2.417 ± 0.193
2. Feelings of Guilt	2.167 ± 0.241	2.250 ± 0.250	2.417 ± 0.229	2.083 ± 0.260
3. Suicide	1.917 ± 0.358	1.833 ± 0.366	2.083 ± 0.260	2.083 ± 0.229
4. Insomnia Early	0.250 ± 0.179	0.333 ± 0.188	0.250 ± 0.179	0.250 ± 0.179
5. Insomnia Middle	0.167 ± 0.167	0.083 ± 0.083	0.167 ± 0.112	0.083 ± 0.083
6. Insomnia Late	0.083 ± 0.083	0.167 ± 0.112	0.250 ± 0.131	0.167 ± 0.112
7. Work and Activities	1.917 ± 0.149	1.917 ± 0.193	1.583 ± 0.149	1.750 ± 0.131
8. Retardation: Psychomotor	2.250 ± 0.218	2.083 ± 0.260	1.917 ± 0.313	2.083 ± 0.336
9. Agitation	0.500 ± 0.195	0.667 ± 0.225	0.583 ± 0.229	0.583 ± 0.260
10. Anxiety(Psychological)	1.083 ± 0.260	1.083 ± 0.260	0.833 ± 0.241	1.000 ± 0.246
11. Anxiety Somatic	1.167 ± 0.241	1.000 ± 0.246	0.833 ± 0.241	0.750 ± 0.250
12. Somatic Symptoms (Gastrointestinal)	0.417 ± 0.193	0.583 ± 0.229	0.583 ± 0.229	0.333 ± 0.188
13. Somatic Symptoms General	0.417 ± 0.193	0.333 ± 0.188	0.417 ± 0.193	0.333 ± 0.188
14. Genital Symptoms	0.500 ± 0.195	0.333 ± 0.188	0.333 ± 0.188	0.417 ± 0.193
15. Hypochondriasis	1.750 ± 0.218	1.500 ± 0.230	1.500 ± 0.195	1.417 ± 0.229
16. Diminished Insight	1.500 ± 0.151	1.197 ± 0.193	1.417 ± 0.193	1.417 ± 0.193
17. Loss of Weight	1.083 ± 0.229	1.000 ± 0.246	1.000 ± 0.246	1.083 ± 0.229
18. Diurnal Variation - Morning or Evening	0.833 ± 0.241	1.000 ± 0.246	0.917 ± 0.229	0.917 ± 0.229
19. Depersonalization and Derealization	1.250 ± 0.279	1.250 ± 0.218	1.417 ± 0.229	1.333 ± 0.188
20. Paranoid Symptoms	1.833 ± 0.297	1.750 ± 0.250	1.500 ± 0.195	1.167 ± 0.207
21. Obsessional and Compulsive Symptoms	0.750 ± 0.218	0.833 ± 0.271	1.000 ± 0.213	1.000 ± 0.275

Student paired t-test: vs. before intake

\*p < 0.05

\*\*p < 0.01

As stated in *KSR International Co. v Teleflex Inc.*, 82 USPQ2d 1385, 1396 (2007), “rejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” Furthermore, the mere fact that references *can* be combined or modified does not render the resultant combination obvious unless the results would have been predictable to one of ordinary skill in the art. *Id.* As described above, Applicants have shown that the present invention achieves unexpected and unpredictable results.

To establish a *prima facie* case of obviousness of a claimed invention, all of the claim limitations must be disclosed by the cited references. As discussed above, Ueda et al. ‘103 in view of Hamilton fail to disclose all of the claim limitations of independent claim 5, and those claims dependent thereon. Accordingly, the combination of references does not render the present invention obvious.

Furthermore, the cited references or the knowledge in the art provide no reason or rationale that would allow one of ordinary skill in the art to arrive at the present invention as claimed. Therefore, a *prima facie* case of obviousness has not been established, and withdrawal of the outstanding rejection is respectfully requested. Any contentions of the USPTO to the contrary must be reconsidered at present.

### **Conclusion**

All of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding rejections and that they be withdrawn. It is believed that a full and complete response has been made to the outstanding Office Action, and as such, the present application is in condition for allowance.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Chad M. Rink, Registration No. 58,258, at the telephone number of the undersigned below to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Director is hereby authorized in this, concurrent, and future replies to charge any fees required during the pendency of the above-identified application or credit any overpayment to Deposit Account No. 02-2448.

Dated: FEB 07 2012

Respectfully submitted,



By \_\_\_\_\_

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